

REMARKS

This Amendment is made to the Official Action mailed March 20, 2009. Claims 3, 8, 16, 17, 19, 21-24, 27-29 and 47-58 have been withdrawn from consideration, without prejudice to their rejoinder or further prosecution in one or more continuation applications. Claims 2-4 and 9 have been cancelled. Claims 1, 7, 30, 35, 37, 42, have been amended. Accordingly, claims 1, 5, 6, 7, 10-15, 18, 20, 25, 26 and 30-46 are currently pending in this patent application. Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the above amendments, and further, in view of the following remarks.

Preliminarily, Applicants note that Group I, covering claims 1-26, 30-34 and 35-46, drawn to dissolvable whitening strips was elected and will be prosecuted on the merits. In addition, the species elected are (a) hydrogen peroxide as a whitening agent; (b) poly(vinylpyrrolidone)-alkyl vinyl ether/maleic anhydride copolymer as a water-soluble or water dispersible polymer system; and (c) a desensitization compound as claimed in claim 18.

In addition, Applicants note that the claims have been amended in order to clarify that the invention is directed to a dissolvable strip for whitening teeth in an oral cavity, comprising about 2 wt% to about 75 wt% of a whitening agent, which is hydrogen peroxide; and a water-soluble or water dispersible polymer system having a poly(vinylpyrrolidone) or any of its copolymers, and at least one other polymer selected from the group consisting of an alkyl vinyl ether/maleic anhydride copolymer, alkyl vinyl ether/maleic acid copolymer, alkali metal or an amine salt of alkyl vinyl ether/maleic acid copolymer, partially or fully cross-linked alkyl vinyl ether/maleic anhydride copolymer, wherein said strip is dissolved by an oral environment containing saliva.

Claims 1 and 7 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Action asserts that the term "PVP derivative" is not adequately described in the disclosure. While Applicants do not agree that the term would not be adequately understood by one of skill in the art, Applicants have amended claims 1, 7 30, 35 and 37 to delete this offending language in order to facilitate allowance of this application. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 4, 7 and 42 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for various reasons. Reconsideration and withdrawal of the rejection are respectfully requested.

As discussed above, claims 1 and 7 have been amended by deleting the term "PVP derivative". In addition, claim 7 has been amended in order to clarify that the water-soluble

or water dispersible polymer system is a poly(vinylpyrrolidone)-alkyl vinyl ether/maleic anhydride copolymer. Applicants submit that this term is clear based upon the description herein. In particular, pages 6 through 9 describe the polymer system in detail, and would be understood by one of skill in the art to be a system comprised of two separate polymers, one being poly(vinylpyrrolidone) and the other polymer being selected from the group consisting of an alkyl vinyl ether/maleic anhydride copolymer, alkyl vinyl ether/maleic acid copolymer, alkali metal or an amine salt of alkyl vinyl ether/maleic acid copolymer, partially or fully cross-linked alkyl vinyl ether/maleic anhydride copolymer, as claimed in amended claim 1. At page 7, first full paragraph, a list of the combination of the first and second polymers is disclosed. Further, at page 8, first full paragraph, discloses that "t[he] combination of the first and second polymers is a combination of PVP and a polymer." One of the specific polymers listed as the other water-soluble or water dispersible polymer is Gantrez®, a well known alkyl vinyl ether/maleic anhydride copolymer.

Claim 4 is cancelled. Claim 42 has been amended by replacing "bleach" with whitening agent, which has antecedent support in independent claim 34. Applicants submit that the rejection under Section 112, second paragraph, has been satisfactorily addressed. Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 2, 7, 9-14, 20, 25, 26, 30 and 31 have been rejected under 35 U.S.C. §103(a), as being unpatentable over U.S. Patent Publication No. 2002/0187181, published December 12, 2002, to Godbey et al. ("Godbey"). Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants urge that the instant invention relates to a dissolvable strip for whitening teeth in an oral cavity, comprising about 2 wt% to about 75 wt% of a whitening agent, which is hydrogen peroxide; and a water-soluble or water dispersible polymer system having a poly(vinylpyrrolidone) or any of its copolymers, and at least one other polymer selected from the group consisting of an alkyl vinyl ether/maleic anhydride copolymer, alkyl vinyl ether/maleic acid copolymer, alkali metal or an amine salt of alkyl vinyl ether/maleic acid copolymer, partially or fully cross-linked alkyl vinyl ether/maleic anhydride copolymer, wherein said strip is dissolved by an oral environment containing saliva. In contrast, Godbey relates to a delivery device for one or more active ingredients, the device including a water-soluble or water-dispersible polymeric carrier, an adhesive, a plasticizer, an active agent and a support layer. Throughout Godbey, the problem to be solved appears to be designing a delivery device that is clear, soft and flexible. This is achieved by a combination of a carrier polymer, an adhesive and a plasticizer.

A long list of suitable water-soluble or water-dispersible polymeric carriers are disclosed, PVA and PVP being preferred. In addition, a long list of potential adhesive agents

is disclosed, including methacrylic acid and maleic anhydride (see, paragraphs [0035] and [0036]. As the Action admits, there is no disclosure of an alkyl vinyl ether/maleic anhydride copolymer as a second polymer in a polymer system. But more importantly, there is absolutely no disclosure of a combination of PVP and an alkyl vinyl ether/maleic anhydride copolymer. Nor is such a combination suggested. At best, the examples disclose the use of PVP as a single polymer carrier for an active agent (see, Examples 1 through 6 and Table 1), or PVA in combination with an adhesive such as poly(N-vinyl lactam) (disclosed in U.S. Patents 5,276,079 and 5,438,988), of PVP in combination with a PEG plasticizer (see, Examples 12-18).

Based upon the long list of polymer choices throughout Godbey's disclosure, one of skill in the art reading Godbey would not be directed to a composition for delivering a tooth whitening agent containing a combination of two water-soluble or water dispersible polymers which are PVP and another polymer selected from the group consisting of an alkyl vinyl ether/maleic anhydride copolymer, alkyl vinyl ether/maleic acid copolymer, alkali metal or an amine salt of alkyl vinyl ether/maleic acid copolymer, partially or fully cross-linked alkyl vinyl ether/maleic anhydride copolymer. A *prima facie* case of obviousness has not been established. Therefore, reconsideration and withdrawal of the rejection are requested.

Claim 33 has been rejected under 35 U.S.C. §103(a), as being unpatentable over Godbey as applied to claims 1, 2, 7, 9-14, 20, 25, 26, 30 and 31, as above, and further, in view of U.S. Patent 6,582,708, issued June 24, 2003, to Sagel et al. ("Sagel"). Godbey does not disclose a whitening strip with a thickness of about 5 μ m to about 2000 μ m. Sagel is used as a general teaching of a whitening strip comprising peroxide, the overall thickness of which is less than about 1mm, i.e., 1000 μ m. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 33 which depends on amended claim 30, is directed to a whitening strip comprising about 2 wt.% to about 75 wt.% of hydrogen peroxide, and a water-soluble or water dispersible polymer system, said polymer system has a poly(vinylpyrrolidone) or any of its copolymers and at least one other polymer selected from the group consisting of an alkyl vinyl ether/maleic anhydride copolymer, alkyl vinyl ether/maleic acid copolymer, alkali metal or an amine salt of alkyl vinyl ether/maleic acid copolymer, partially or fully cross-linked alkyl vinyl ether/maleic anhydride copolymer, and which strip has a thickness between about 5 μ m to about 2000 μ m. The distinctions between Godbey and this invention have been discussed above.

While Sagel discloses a tooth whitening strip, the thickness of the strip as disclosed in col. 9, lines 35-40, is relevant to strips containing shallow pockets which provide additional reservoirs for the active substance. In addition, the hydrogen peroxide active agent is

delivered as part of an aqueous gel, preferably containing a cellulose gelling agent. Neither of these disclosures is in any way relevant to the dissolvable whitening strip claimed herein.

Nothing in Sagel would direct a skilled artisan to modify the teaching in Godbey in order to arrive at the instant invention. Therefore, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection are requested.

Claims 5 and 6 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Godbey as applied to claims 1, 2, 7, 9-14, 20, 25, 26, 30 and 31, as above, and further, in view of U.S. Patent 4,971,782, issued November 20, 1990, to Rudy et al. ("Rudy"). Reconsideration and withdrawal of the rejection are respectfully requested.

The Action concedes that Godbey does not teach a whitening agent which is encapsulated or dissolves by interaction of the encapsulation shell with saliva. Rudy discloses peroxide and sodium bicarbonate compositions and methods for stabilizing such compositions. One method to provide stability to the active ingredients is by encapsulating the peroxide and/or sodium bicarbonate in an oleophilic material, defined as having an affinity for oils rather than water. A long list of such ingredients is disclosed at col. 6, lines 54-64, including carbowax, geletin, Carbopol®, mineral oil, etc.

This is in contrast to the instant invention that contemplates the hydrogen peroxide being encapsulated in a water-soluble or water dispersible shell for purposes of controlling the delivery rate of the hydrogen peroxide and not as a means to prevent decomposition by an aqueous environment. The polymers used to encapsulate the hydrogen peroxide in the instant invention are water soluble or water dispersible, the opposite of oleophilic. Rudy actually teaches away from the instant encapsulation material.

Therefore, Rudy does not provide the requisite teaching or suggestion to a skilled artisan which is needed to modify the teaching in Godbey in order to arrive at the instant invention. A *prima facie* case of obviousness has not been established by this combination of citations. Reconsideration and withdrawal of the rejection are requested.

Claims 4, 15, 18, 27, 32 and 34-36 have been rejected under 35 U.S.C. §103(a), as being unpatentable over Godbey and Rudy as applied to claims 5 and 6, and further in view of U.S. Patent Publication No. 2003/0228264, published December 11, 2003, to Perna ("Perna"). Reconsideration and withdrawal of the rejection are respectfully requested.

Perna teaches a dissolvable substrate labelled 102 in the figures. The substrate materials specifically taught by Perna are gelatin, cellulose and carboxymethylcellulose, carbohydrate, fat, protein, natural or synthetic wax, dissolvable resin and hydrogel. The Action concedes that Perna does not disclose a single or multi-layered dissolvable strip containing PVP and an alkyl vinyl ether/maleic anhydride copolymer.

Godbey is distinguished above. Specifically, there is no disclosure of a combination of PVP and an alkyl vinyl ether/maleic anhydride copolymer in Godbey. Rudy, as discussed above, teaches away from the instant encapsulation materials. Therefore, even if Rudy (used for teaching encapsulation) and Perna (used for teaching multiple layers) were combined with Godbey, the instant invention would not be achieved. No fair reading of the citations, alone or in combination, teach the instant invention. A *prima facie* case of obviousness has not been established. Therefore, reconsideration and withdrawal of the rejection are requested.

In view of the foregoing, favorable reconsideration of claims 1, 7, 30, 35, 37, 42, favorable consideration of claims 5, 6, 10-15, 18, 20, 25, 26, 31-34, 36, 38-41 and 43-46, and allowance of this application with claims 1, 5, 6, 7, 10-15, 18, 20, 25, 26 and 30-46, are earnestly solicited. Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully Submitted,



Nora Stein-Fernandez
Attorney for Applicants
Registration No.36,689

GlaxoSmithKline Corporation
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5044
Facsimile (610) 270-5090